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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,109	10/01/2001	Cordula Hopmann	02481.1751	4743

7590 11/24/2004

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Washington, DC 20005-3315

EXAMINER
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PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/966,109	<b>Applicant(s)</b> HOPMANN ET AL.	
	<b>Examiner</b> Elli Peselev	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-19, 21 and 22 is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the Office Action of June 22, 2004.

Applicant's arguments filed October 15, 2004 have been considered but have not been found persuasive.

Applicant contends that to determine enablement, the Examiner is required to assess whether one skilled in the art can make and use the invention without undue experimentation. This argument has not been found persuasive.

(A) The breadth of the claim: the claim encompasses the treatment of schizophrenia, Parkinson's disease and Alzheimer's disease, while providing no evidence that the claimed method is effective for treating said diseases.

(B) The nature of the invention: the treatment of said diseases is difficult and highly unpredictable

( C ) The state of the prior art: Binder et al (Biol psychiatry, vol. 50 pp.856-872 (2001)) disclose that the data presented "suggest possible therapeutic effects of NT agonists" (page 866). Antonelli et al (Journal of Neuroscience Research 70:766-773 (2202)) disclose that "selective neurotensin antagonists could provide a novel therapeutic approach for the treatment of neurodegenerative disorders, such as Parkinson's disease" (page 766). The International Patent WO 94/10151 discloses compounds which are useful in attenuating the effect of peptide hormone neurotensin, and hence in the treatment of such disease as Alzheimer's (page 28). However, said patent provides no evidence to support said statement. The teaching by the prior art is

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at best speculative and it would take an additional experimentation to determine which specific compounds are useful against which specific diseases.

(D) The level of one of ordinary skill is such that further experimentation is required in order to determine the effectiveness of the claimed method for the treatment of schizophrenia, Parkinson's disease and Alzheimer's disease.

(E) The level of predictability in the art: due to the differing underlying causes which give rise to various diseases encompassed by the instant claim, there is a good reason to doubt that claimed method is effective in the treatment humans based on an assay showing the affinity for the neurotensin receptor.

(F) The amount of direction provided by the inventor: the only direction provided by the inventor is in the Example 4 on pages 24-25 of the specification which that the compounds encompassed by the instant claims have affinity for the neurotensin receptor.

(G) The existence of working examples: no working examples are provided which show that the activity of the claimed compounds in the treatment of schizophrenia, Parkinson's disease or Alzheimer's disease

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclose: since that prior art provides only speculative statements as to the usefulness of neurotensin agonists in the treatment of biological diseases, further experimentation is needed to determine the effectiveness of the claimed method.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**ELLI PESELEV**  
**PRIMARY EXAMINER**  
**GROUP 1800**